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PATENT
Customer No. 22,852
Attorney Docket No. 08201.0024-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
MacKay et al.	Group Art Unit: 1644
Serial No.: 10/045,574	Examiner: Haddad, Maher M.
Filed: November 7, 2001	
For: BAFF, INHIBITORS THEREOF AND THEIR USE IN THE MODULATION OF B-CELL RESPONSE AND TREATMENT OF AUTOIMMUNE DISORDERS	

Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated March 24, 2003, the Examiner required restriction under 35 U.S.C. § 121 between sixty groups:

Group I - Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunoglobulin production, and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2

Group II - Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunoglobulin production, and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 424, subclass 140.1 and Class 514, subclass 2

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Group III - Claims 1-6 and 8-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunoglobulin production, and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a GAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2

Group IV - Claims 1-9, drawn to a method of stimulating B-cell growth, stimulating immunoglobulin production, co-stimulating B-cell growth and immunoglobulin production, and stimulating dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-CD40 ligand molecule, classified in Class 424, subclass 140.1; Class 514, subclass 2

Group V - Claims 10-15, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co-inhibiting B-cell growth and immunoglobulin production, and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group VI - Claims 10-15, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co-inhibiting B-cell growth and immunoglobulin production, and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of a recombinant. inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2 and 424, subclass 140.1

Group VII - Claims 10-16, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co-inhibiting B-cell growth and immunoglobulin production, and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group VIII - Claims 10-13 and 17, drawn to a method of inhibiting B-cell growth, inhibiting immunoglobulin production, co-inhibiting B-cell growth and immunoglobulin production, and inhibiting dendritic cell-induced B-cell growth and maturation in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1; Class 514, subclass 2

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Group IX - Claims 18 and 21-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2

Group X - Claims 18 and 21-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti-T antibody, classified in Class 514,subclass 2 and Class 424, subclass 140.1

Group XI - Claims 18, and 21-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2

Group XII - Claims 18 and 21-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof and an anti CD40 ligand molecule, classified in Class 514, subclass 2 and Class 424, subclass 140.1

Group XIII - Claims 18 and 24-25, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group XIV - Claims 18 and 21-22, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2

Group XV - Claims 18 and 26, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XVI - Claims 18 and 27, drawn to a method of treatment of an autoimmune disease comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1

Group XVII - Claims 19-22, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein

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the BAFF-related molecule is a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 44

Group XVIII - Claims 19-22, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF-ligand or an active fragment thereof and an anti-T antibody, classified in Class 514, subclass 44

Group XIX - Claims 19-22, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF-ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 44

Group XX - Claims 19-23, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a GAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is a BAFF ligand or an active fragment thereof and an anti-CD40 ligand molecule classified in Class 514, subclass 44

Group XXI - Claims 19-20 and 24-25, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein the BAFF-related molecule is an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 44

Group XXII - Claims 19-22, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein the BAFF-related molecule is a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 44

Group XXIII - Claims 19-20 and 26, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule and expressing said gene in said cell, wherein the BAFF-related molecule is an antibody specific for

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BAFF-ligand or an active fragment thereof, classified in Class 514, subclass 44

Group XXIV - Claims 19-20 and 27, drawn to a method of treating a disorder related to BAFF-ligand comprising introducing into a desired cell a therapeutically effective amount of a vector containing a gene encoding for a BAFF-related molecule, and expressing said gene in said cell, wherein the BAFF-related molecule is an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 514, subclass 44

Group XXV - Claim 28, drawn to a method of inducing a cell death comprising the administration of an went capable of interfering with the binding of a BAFF-ligand to a receptor, classified in Class 514, subclass 2, and Class 424, subclass 140.1

Group XXVI - Claims 29 and 33, drawn to a method of treating, suppressing or altering an immune response involving a signaling pathway between a BAFF-ligand and its receptor comprising the step of administering an effective amount of an agent capable of interfering with the association between the BAFF-ligand and its receptor, classified in Class 514, subclass 2, and Class 424, subclass 140.1

Group XXVII - Claim 30, drawn to a method of inhibiting inflammation comprising the step of administering a therapeutically effective amount of an antibody specific for a BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XXVIII - Claim 31, drawn to a method of inhibiting inflammation comprising the step of administering a therapeutically effective amount of an antibody specific for a BAFF ligand receptor or epitope thereof, classified in Class 424, subclass 140.1

Group XXIX - Claim 32, drawn to a method of regulating hematopoietic cell development comprising the step of administering a therapeutically effective amount of a BAFF ligand or an active fragment thereof, classified in Class 514, subclass 2

Group XXX - Claims 34-37 and 40-41, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group XXXI - Claims 34-35 and 40-41, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth

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inhibitor is a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 514, subclass 2

Group XXXII - Claims 34-35, 38, and 40-41, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XXXIII - Claims 34-35 and 39-41, drawn to method of treating hypertension in an animal comprising the step of administering a therapeutically effective amount of a B-cell growth inhibitor, wherein the B-cell growth inhibitor is an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1

Group XXXIV - Claim 42-44, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group XXXV - Claim 42-44, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective a recombinant, inoperative BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2

Group XXXVI - Claim 42-44, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an antibody specific for BAFF ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XXXVII - Claim 42-44, drawn to method of treating cardiovascular disorders in an animal comprising the step of administering a therapeutically effective an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1

Group XXXVIII - Claims 45-46, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1 and Class 514, subclass 2

Group XXXIX - Claims 45-46, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of a recombinant inoperative BAFF-ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2

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Group XL - Claims 45-46, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF-ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XLI - Claims 45-46, drawn to method of treating renal disorders in an animal comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF-ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1

Group XLII - Claim 47, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an anti-BAFF ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group XLIII - Claim 47, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of a recombinant inoperative BAFF-ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1, and Class 514, subclass 2

Group XLIV - Claim 47, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF-ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group XLV - Claim 47, drawn to a method of treating B-cell lympho-proliferate disorders comprising the step of administering a therapeutically effective amount of an antibody specific for BAFF-ligand receptor or an epitope thereof, classified in Class 424, subclass 140.1

Group XLVI - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF-ligand or an active fragment thereof, classified in Class 514, subclass 2

Group XLVII - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF-ligand or an active fragment thereof and an anti-T antibody, classified in Class 514, subclass 2, and Class 424, subclass 140.1

Group XLVIII - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF-ligand or an active fragment thereof and a CD40 ligand, classified in Class 514, subclass 2 and Class 424, subclass 140.1

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Group XLIX - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a BAFF-ligand or an active fragment thereof and an anti-CD40 ligand molecule, classified in Class 514, subclass 2 and Class 424, subclass 140.1

Group L - Claims 47-50, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an anti-BAFF-ligand molecule or an active fragment thereof, classified in Class 424, subclass 140.1

Group LI - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering a recombinant, inoperative BAFF-ligand molecule or an active fragment thereof, classified in Class 514, subclass 2

Group LII - Claims 48-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an antibody specific for BAFF-ligand or an active fragment thereof, classified in Class 424, subclass 140.1

Group LIII - Claims 48, 50-51, drawn to a method of treating B-cell production in the treatment of immunosuppressive diseases comprising the step of administering an antibody specific for BAFF ligand receptor or an epitope thereof, classified in Class 514, subclass 2 and Class 424, subclass 140.1

Group LIV - Claims 52-55, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is a soluble BAFF receptor molecule, wherein the BAFF receptor is TACI; classified in Class 514, subclass 2

Group LV - Claims 52-54 and 56, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is a soluble BAFF receptor molecule, wherein the BAFF receptor is BCMA; classified in Class 514, subclass 2

Group LVI - Claims 52-54 and 57, drawn to a method for treating or reducing the advancement, severity, or effects of Sjogren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is a soluble BAFF receptor molecule, wherein the BAFF receptor is BAFF-R; classified in Class 514, subclass 2

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Group LVII - Claims 52-53 and 58, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is an antibody directed against BAFF-ligand; classified in Class 424, subclass 143.1

Group LVIII - Claims 52-53 and 59-60, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is an antibody directed against BAFF-receptor TACI; classified in Class 424, subclass 143.1.

Group LIX - Claims 52-53, 59 and 61, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is an antibody directed against BAFF-receptor BCMA; classified in Class 424, subclass 143.1.

Group LX - Claims 52-53, 59 and 62, drawn to a method for treating or reducing the advancement, severity, or effects of Sjögren's syndrome in a patient comprising administering a phannaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is an antibody directed against BAFF-receptor BAFF-R; classified in Class 424, subclass 143.1

Applicants provisionally elect with traverse to prosecute Group LVI, claims 52-53 and 57 drawn to a methods for treating or reducing the advancement, severity or effects of Sjögren's syndrome in a patient comprising administering a pharmaceutical composition comprising a BAFF blocking agent, wherein the BAFF blocking agent is a soluble BAFF receptor molecule, which is BAFF-R.

For a restriction requirement to be proper, a showing of serious burden on the Examiner is required. A serious burden may be *prima facie* shown by separate classification, separate status in the art, or a different field of search. *See* Manual of Patent Examining Procedure (MPEP) §§ 802-803. When inventions are classified in

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the same class and subclass, MPEP § 802.02 requires the Examiner to show different fields of search, e.g., that it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists. The present restriction requirement provides no such showing. The Examiner merely alleges that a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct steps. The Examiner does not explain what structural differences in the "products" or "steps" would necessitate a field of search where no pertinent art to the other subject exists. Thus, the Examiner has failed to make a *prima facie* showing that such a different field of search exists.

No fee is believed to be due with this response. If any fee is due, please charge the fees to deposit account 06-0916.

Respectfully submitted,

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Dated: April 22, 2003

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